

Consumer Information on: Abbott RealTime HBV Assay - P080026

U.S. Food & Drug Administration

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.



Product Name: Abbott RealTime HBV Assay

PMA Applicant: Abbott Molecular Inc.

Address: 1300 E. Touhy Avenue, Des Plaines, IL 60018

Approval Date: August 13, 2010

Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf8/P080026a.pdf [1]

What is it? Abbott RealTime HBV is a laboratory test kit that measures the amount of hepatitis B viral DNA in the blood of an individual infected by the [hepatitis B virus \(HBV\)](#) [2]. Viral DNA is the genetic material from the hepatitis B virus. The individual's hepatitis B viral DNA is measured before beginning treatment and during treatment to assess an individual's response to the treatment. This test is used with the Abbott *m2000sp* and *m2000rt* automated instruments and the results from the Abbott RealTime HBV test must be used in combination with other relevant clinical and laboratory findings.

How does it work? A sample of a patient's blood is obtained and sent to a clinical laboratory. DNA is separated from the cells in the blood sample and mixed with test chemicals using the automated Abbott *m2000sp* system. The resulting mixture is put into the *m2000rt* analyzer. The *m2000rt* analyzer calculates the amount of HBV DNA in the patient's blood based on the amount of produced light measured by the analyzer after completion of the reaction. Measurement of the amount of HBV DNA in the blood together with clinical information and other laboratory blood tests used by physicians help determine a patient's response to treatment.

When is it used? This is a laboratory test used for adult individuals infected with the hepatitis B virus, to evaluate the treatment, together with other laboratory and clinical information.

What will it accomplish? Test results help determine an individual's response to treatment and aid in the management of patients with HBV infection undergoing anti-viral therapy.

When should it not be used? This lab test should not be used if it is not ordered by a physician. The assay should not be used to determine if a person is infected with the hepatitis B virus or to determine the stage of HBV infection. It should not be used to screen blood or blood products for transfusion. And, it should not be used to predict the outcome of anti-viral treatment.

Additional information: Summary of Safety and Effectiveness and labeling are [available online](#) [3].

Other Resource:

- [Centers for Disease Control and Prevention \(CDC\) - Hepatitis B Information for the Public](#) [4]

[SOURCE](#) [5]

Source URL (retrieved on 01/25/2015 - 8:14pm):

http://www.mdtmag.com/news/2010/10/consumer-information-abbott-realtime-hbv-assay-p080026?qt-recent_content=0

Links:

[1] http://www.accessdata.fda.gov/cdrh_docs/pdf8/P080026a.pdf

[2] <http://www.nlm.nih.gov/medlineplus/hepatitisb.html>

[3] <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P080026>

[4] <http://www.cdc.gov/hepatitis/B/>

[5] <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm227914.htm>